

Application No. 09/975,873  
Amendment dated August 5, 2003  
Reply to Office Action dated May 5, 2003

### REMARKS

In view of the preceding amendments and the following remarks, Applicants respectfully request the Examiner to reconsider the patent application identified above and withdraw the present rejection. Claims 1-8 are pending in the present application, all of which stand currently rejected.

#### Specification:

The Examiner objected to the drawings under 37 C.F.R. §1.83(a) for a reference numeral. Applicant has made an amendment correcting a typographical error in Figure 1, to indicate that reference numeral 23 should have been 28. Accordingly, no new matter has been added.

#### 35 U.S.C. §102:

The Examiner rejected Claims 1-7 under 35 U.S.C. §102(b) on the basis of Gunderson (U.S. 5,776,142), referred to in this response as the "'142 patent". The Examiner rejected Claim 8 under 35 U.S.C. §102(b) on the basis of Olson (U.S. 5,906,619), referred to in this response as the "'619 patent".

Both the '142 patent and the '619 patent teach some form of screw thread mechanism in which "the pitch of the threads may vary over the length of the screw":

In another example, the pitch of the threads may vary over the length of the screw. Referring now to FIG. 11, where one embodiment of a variable pitch screw 126 is depicted. The threads 128a in Section I of the screw 126 have a larger pitch or spacing than do the threads 128b in Section II. One potential advantage for such a design is that axial compression, i.e., movement of the ends of the stent towards each other, can be increased at the beginning of the release sequence when the thread pitch is larger, followed by more precise control over the rate of radial expansion of the stent when the thread pitch is smaller. Other modifications in the use of varying thread pitch will also be possible, e.g., providing a smaller thread pitch first followed by a larger pitch, continually varying the pitch over the length of the screw portion, etc.

('142 patent, col. 8, lines 45-59.)

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A variable displacement delivery system 110 is illustrated in FIGS. 10 and 11. Variable pitch delivery system 110 includes many of the same components described above, but makes use of a handle 112 having variable pitch internal threads 114. Variable threads 114 have a relatively small pitch adjacent the distal end of handle 112 so that each rotation of the handle moves sheath 32 proximally a relatively small axial distance during the initial phases of deployment. This provides an increased mechanical advantage between the handle and the sheath, helping the physician to overcome the large static frictional forces between the prosthesis and the surrounding sheath. This enhanced mechanical advantage also helps overcome any invagination of the prosthetic frame into the surrounding sheath material. As a result, the distal end of the prosthesis (which is deployed first) will be very gradually released, allowing the physician to verify the accuracy of the deployment position as the prosthesis initially engages the surrounding body lumen. These distal threads will generally have a pitch of between about 0.125 and 0.375, providing a mechanical advantage in the range from about 4:1 to about 2.5:1.

('619 patent, col. 7, line 56 to col. 8, line 9.)

As described above, distal pitch 128 is significantly less than a proximal pitch 130, so that rotation of the handle at a constant speed results in increased axial speed of the sheath relative to the prosthesis. Each rotation of handle 112 preferably moves sheath 32 an axial distance of about 0.25 inches when sheath 32 is adjacent covered position 118, while this same rotation of the handle preferably moves the sheath an axial distance of about 0.75 inches when the sheath is adjacent the deployed position 120. In other words, in the exemplary embodiment distal pitch 128 is about 0.25 inches, while proximal pitch 130 is about 0.75 inches. The threads may vary linearly between the proximal and distal ends (as illustrated in FIG. 12), or may vary substantially stepwise as illustrated in FIG. 10. Still further alternatives are possible, such as a quadratic variation in pitch along the axial length of the threads.

('619 patent, col. 8, lines 49-64.)

Applicants respectfully submit that the cited references fail to teach or suggest the present invention, as recited in the Claims. For example, Claim 1 includes the following limitations, among others:

the handle having a first and second independently moveable actuator for adjusting the relative longitudinal positions of the inner shaft and the outer sheath, each of the first and second actuators providing a different amount

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of mechanical advantage between an input to one of the first and second actuators by a physician and a resulting relative longitudinal position of the inner shaft and the outer sheath respectively.

However, the pitch at any point along the variable pitch screw threads of the '142 and '619 patents is not "independently moveable" with respect to the pitch at any other point of the screw thread. In other words, whatever screw thread pitch patterns are disclosed in the '142 and '619 patents, the pitch pattern cannot be changed in a "real-time" fashion during use of the device by a physician.

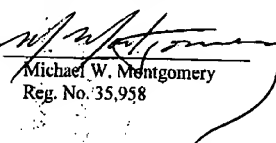
In contrast, with the present invention, the physician may select to use either the first or second actuator at any time during delivery of the medical device.

Applicants respectfully request the Examiner to allow the present invention.

Respectfully submitted,  
Attorney for Applicants

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By:

  
Michael W. Montgomery  
Reg. No. 35,958

Johnson & Johnson  
Law Department  
One Johnson & Johnson Plaza  
New Brunswick, New Jersey 08933  
(786) 313-2922